DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION DRUG TESTING ADVISORY BOARD

March 7 - 8, 2006

The Drug Testing Advisory Board was convened for its meeting at 8:30 a.m. on March 7, 2006, in the SAMHSA Building (Sugarloaf Room), 1 Choke Cherry Road, Rockville, Maryland.

In accordance with the provisions of Public Law 92-463, the meeting was open to the public on March 7 from 8:30 a.m. to 11:30 a.m. The meeting was closed to the public on March 7 from 11:30 a.m. until adjournment on March 8 at 11:45 a.m. to develop the final revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs and to discuss specific laboratory certification issues.

Board members present:

Robert Stephenson II, Chairman

Dr. Alberto Gutierrez

Dr. Estela Estape

Dr. Jennifer Collins

Dr. Henry Nipper

Lisa Tarnai

Dr. Frederick Fochtman

Dr. William Ferguson Reid

Pat Pizzo

Dr. David Kuntz

Others present for all or a portion of the meeting were:

Dr. Walter Vogl, DWP, CSAP

Charles LoDico, DWP, CSAP

Ron Flegel, DWP, CSAP

Dr. John Mitchell, RTI International

Dr. Mike Baylor, RTI International

Dr. Craig Sutheimer, RTI International

Dr. Jeri Ropero-Miller, RTI International

Dr. Yale Caplan, DOT Consultant

Tim McCune, NRC

COL Ron Shippee, DoD

Ed Jurith, ONDCP

TOPICS DISCUSSED IN OPEN SESSION

Note: The transcript for the open session is available on the Internet at: http://workplace.samhsa.gov

Opening Remarks

Mr. Stephenson convened the open session of the Board meeting.

The Board members and invited guests introduced themselves.

Mr. Stephenson pointed out a display board, located in the back of the room, that had a representative sample of adulterants and substitution products being sold on the Internet and in various magazines. Donors may be using these products to affect the testing of urine specimens as well as hair and oral fluid specimens.

Pat Pizzo (Board member) thanked the Division of Workplace Programs (DWP) and RTI International (NLCP Contractor) for assisting Kroll LSI to regain its certification after the laboratory was shut down by the damage from Hurricane Katrina.

HHS Update

Dr. Vogl (DWP) mentioned these items.

First, RTI International is planning to give an NLCP workshop on June 22-24, 2006, that will provide a detailed discussion of the NLCP and issues impacting on forensic drug testing laboratories. Although the workshop is primarily focused on urine testing, it may be beneficial for individuals working in laboratories that test alternative specimens to become fully aware of the laboratory certification process.

Second, the DWP website continues to be updated and the format transferred from one software package to another. Until the conversion is complete, workplace.samhsa.gov will automatically change to show dwp.samhsa.gov.

Third, on February 22, 2006, we published a notice in the <u>Federal Register</u> regarding the burden hours associated with completing the Federal drug testing custody and control form (Federal CCF) that is used by Federal agencies and DOT-regulated employers to document the collection of urine specimens. This notice gives the public 60 days to submit comments. After the public comment period ends, an entire document package will be sent to the Office of Management and Budget (OMB) requesting approval to extend the expiration date for the form for 3 years.

NRC Update

Mr. McCune (NRC) provided comments on the status of NRC's revision of its Part 26 Fitness For Duty rule. One area of concern is the establishment of drug and alcohol testing requirements for licensees that have plants under construction. Within a few weeks, the NRC will hold a public meeting to discuss these specific requirements because the proposed rule was not fully understood when it was released for public comment.

DoD Update

COL Shippee (DoD) stated that the military services have been evaluating the use of collecting and testing oral fluid specimens at military entrance processing stations (MEPS) for the past year and a half. The results of the oral fluid specimens are being compared to the results from the urine specimens that are collected at the same time. When the comparative study is completed, the results will be shared with DWP.

DOT Update

Dr. Vogl presented two items that Mr. Ellis (DOT) wanted to share with the Board.

First, DOT received over 200 public comments from 27 different commenters on its proposal to incorporate specimen validity testing into the DOT regulations. DOT is currently organizing the comments and working on the development of the final regulation.

Second, DOT is about to release a notice of proposed rulemaking to allow marriage and family therapists, who are credentialed, to serve as substance abuse professionals (SAPs) as described in the DOT workplace regulation.

Pilot Performance Testing (PT) Program for Hair

Dr. Mitchell (RTI International) presented an update on the results of the PT samples sent to hair testing laboratories for cycles 9 through 11. This presentation focused on the design of the PT samples, the results reported by the laboratories participating, a comparison of the test results to the requirements in the proposed Guidelines of April 2004, and a discussion of future plans. The PT samples included the analytes in the urine program as well as several proposed analytes. The analyte concentrations in the PT samples ranged from 50% below the cutoff, at the cutoff, and 200% above the cutoff. The laboratories were directed to only conduct confirmatory testing and were instructed not to conduct any decontamination procedures. For specific results, see the PowerPoint slides attached to the meeting transcript that is on this website. In general, a large variation continues to exist among the participant laboratories for the following possible reasons: reference materials are not commercially available, PT sample composition may vary, and quality control procedures vary among the laboratories.

Pilot Performance Testing (PT) Program for Oral Fluid

Dr. Mitchell (RTI International) presented an update on the results of the PT samples sent to the

oral fluid testing laboratories for cycles 4 through 6. This presentation focused on the design of the PT samples, the results reported by the laboratories participating, a comparison of the test results to the requirements in the proposed Guidelines of April 2004, and a discussion of future plans. The PT samples included the analytes in the urine program as well as several proposed analytes. The analyte concentrations in the PT samples ranged from 50% below the cutoff, at the cutoff, and 200% above the cutoff. The laboratories were directed to only conduct confirmatory testing. For specific results, see the PowerPoint slides attached to the meeting transcript that is on this website. In general, excessive variation continues to exist among the participant laboratories for the following possible reasons: reference materials are not commercially available, laboratories have not developed procedures that are accurate and precise, some of the analytes in the oral fluid PT samples are not stable, and quality control procedures vary among the laboratories.

Public Comments

Mr. Steven Soifer provided a statement on behalf of the International Paruresis Association expressing concern regarding the time it is taking to publish the final Guidelines for alternative specimen collection and testing.

Mr. Paul Speidel (Psychemedics Corporation) simply wanted to know where the Guidelines were.

Mr. Stephenson responded by describing the rulemaking process and indicated that DWP and this Board have done everything to ensure that the process moved forward as quickly as possible.

The open session ended at 11:30 a.m.

TOPICS DISCUSSED IN CLOSED SESSION

The Board approved the Minutes for the December 13 - 14 meeting.

The Board discussed the final revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Program.

Other topics discussed by the Board included specific Federal agency specimen results, confirmatory drug test batch issues, specimen validity test results, and analytical instrumentation issues.

Adjournment

The meeting adjourned at 11:45 a.m. on March 8.

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

/signed/

Donna M. Bush, Ph.D., D-ABFT Executive Secretary, DTAB

/signed/

Robert L. Stephenson II, M.P.H. Chair, DTAB

These minutes will be formally considered, amended, and approved by the Board using email.